

**IN THE UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF PENNSYLVANIA**

MAUREEN PIEKANSKI

*Plaintiff,*

v.

ALEX AZAR II, in his official capacity  
as the Secretary of the Department of  
Health and Human Services,

*Defendant.*

Case No. 3:20-cv-00687-RDM

(Hon. Robert D. Mariani)

Electronically Filed

**FIRST AMENDED COMPLAINT**

Plaintiff Maureen Piekanski (“Plaintiff”) brings this action against Defendant Alex Azar, in his official capacity as Secretary of the United States Department of Health and Human Services (hereinafter, “the Secretary”), to obtain injunctive relief for violation of federal law. Plaintiff makes the following allegations based on the investigation of counsel, information and belief, and on personal knowledge.

**SUMMARY**

1. This case presents a simple question: is the Secretary bound by the Supreme Court’s decision in *Astoria Federal Savings & Loan v. Solimino*, 501 U.S. 104 (1991) such that collateral estoppel can apply against the Secretary where the Secretary has previously litigated, and lost, an issue against the same party?

2. Likewise, having previously determined multiple times that coverage of a medical device to treat Plaintiff's extremely lethal form of brain cancer was appropriate, is it arbitrary and capricious for the Secretary to decide otherwise when the facts and/or circumstances have not changed?

3. In the case at issue here, the Secretary asserts that his regulations (rather than the directives of the Supreme Court) preclude collateral estoppel and that month-to-month differing decisions (where the facts and/or circumstances have not changed) on Plaintiff's life-saving care are not arbitrary and capricious. Plaintiff asserts that those positions are wholly without merit.

4. Tragically, the Plaintiff is suffering from a particularly deadly form of brain cancer, glioblastoma multiforme (GBM),<sup>1</sup> and she is seeking coverage for life-saving treatment. In a particularly cruel twist, on a month-to-month basis, the Secretary is forcing the Plaintiff to repeatedly prove that she is entitled to the treatment and the Secretary's decisions differ with no predictable pattern. Thus, the Secretary is playing a game of chance with the Plaintiff's life – maybe this month she will get life-saving treatment; maybe she won't.

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<sup>1</sup> Former Senators Edward Kennedy and John McCain also suffered, and died from, this kind of cancer.

### **JURISDICTION & VENUE**

5. This Court has jurisdiction over this action pursuant to 42 U.S.C. §§ 405(g) and 1395ff. The Plaintiff is filing suit after the Medicare Appeals Council (“MAC”) granted Plaintiff’s request for escalation to Federal district court, as the Medicare Appeals Council was unable to issue a decision within its adjudicatory timeframe on her appeal of an Administrative Law Judge decision (acting on behalf of the Secretary) denying coverage of her Medicare claims. Therefore, Plaintiff has exhausted her administrative remedies. The amount-in-controversy is more than \$1,630 (42 U.S.C. §§ 1395ff(b)(1)(E)(i) and 1395ff(b)(1)(E)(iii)), and this suit was filed within 60 days of the Secretary’s Order Granting Request for Escalation.

6. Venue is proper in this district pursuant to 42 U.S.C. § 1395ff(b)(2)(C)(iii) because Plaintiff resides within this judicial district.

### **PARTIES**

7. Plaintiff Maureen Piekanski is an individual, resident and citizen of the State of Pennsylvania. Mrs. Piekanski is eligible for Medicare on the basis of age (or disability) as previously determined by the Secretary.

8. Defendant Alex Azar is sued in his official capacity as the Secretary of the Department of Health and Human Services.

## **LEGAL BACKGROUND**

9. In *Astoria Federal Savings & Loan Assoc. v. Solimino*, 501 U.S. 104, 107-08 (1991), the Supreme Court held that:

We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

10. The application of collateral estoppel to agency determinations (even against agencies) has been affirmed in numerous cases. *See, e.g., Brewster v. Barnhart*, 145 Fed. App'x. 542 (6<sup>th</sup> Cir. 2005) (SSA ALJ bound by prior work determination).

## **FACTUAL BACKGROUND**

### **A. Tumor Treatment Field Therapy (TTFT)**

11. Glioblastoma multiforme (GBM) is an unusually deadly type of brain cancer. Without treatment, survival is typically 3 months. With traditional forms of

treatment, the survival rate at 2 years after treatment is ~31%, while at five years, only ~5% of patients are living.

12. More recently, treating GBM using alternating electric fields has been developed. This is known as tumor treatment field therapy (TTFT). Alternating electric fields interfere with tumor cell replication and have been shown to dramatically increase the period during which the GBM does not progress, as well as overall survival rates. Indeed, TTFT has proven so effective that, in late 2014, a randomized clinical trial of TTFT was suspended because it would have been unethical to withhold TTFT treatment from the control group.<sup>2</sup>

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<sup>2</sup> In much scientific research, study participants are randomly assigned to “control” and “test” groups. The “control” group does not receive the treatment being tested. In contrast, the “test” group does. Proceeding in this way facilitates the determination of which effects, if any, are the result of the tested treatment as opposed to normal variation among the study participants. During the course of a study, interim results are frequently measured to determine whether the study is proceeding as planned and whether any changes are needed. When the interim results indicate that the tested treatment has a significant effect on health or safety, either negative or positive, ethical guidelines dictate that the study should be halted. Thus, if the interim results indicate that the tested treatment was significantly more likely to result in death than the control group, the study would be halted and the treatment no longer given to the “test” group. Likewise, if the interim result indicated that the tested treatment was literally life-saving, the study would be halted and the treatment would be made available to the “control” group. In those circumstances, withholding the treatment from the “control” group would be unethical.

13. In ground-breaking papers published in the Journal of the American Medical Association (JAMA)<sup>3</sup> in 2015 and 2017, TTFT was shown to increase the 2-year survival rate by more than 38% and to nearly triple the five-year survival rate.<sup>4</sup>

14. As reported, TTFT was the first significant advance in treating GBM in more than a decade. TTFT has become the standard of care for treating GBM and essentially all private insurers cover TTFT. TTFT saves and/or extends GBM patients' lives, in some instances, by years. Between January 2016 and December 2018, at least 93 scientific papers were published demonstrating the effectiveness of TTFT. It is given a level one recommendation in the National Comprehensive Cancer Network (NCCN) guidelines, *i.e.*, there is consensus, among the experts, based on a high level of evidence, that TTFT is a recommended intervention.

15. The sole supplier of the equipment that delivers TTFT is Novocure, Inc. which manufactures the Optune<sup>TM</sup> system. The Optune system is rented on a monthly basis. Thus, after a patient is prescribed the Optune system, they will have

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<sup>3</sup> The Journal of the American Medical Association (JAMA) is widely regarded as one of the most prestigious medical journals in the United States and the world.

<sup>4</sup> See *Stupp, et al.*, "MAINTENANCE THERAPY WITH TUMOR-TREATING FIELDS PLUS TEMOZOLOMIDE VS. TEMOZOLOMIDE ALONE FOR GLIOBLASTOMA: A RANDOMIZED CLINICAL TRIAL", JAMA, Vol. 314, No. 23, pgs. 2535-43 (December 15, 2015); *Stupp, et al.*, "EFFECT OF TUMOR TREATING FIELDS PLUS MAINTENANCE TEMOZOLOMIDE VS. MAINTENANCE TEMOZOLOMIDE ALONE ON SURVIVAL IN PATIENTS WITH GLIOBLASTOMA", JAMA, Vol. 318, No. 23, pgs. 2306-2316 (December 19, 2017).

monthly claims for Medicare coverage. Sadly, there is no known cure for GBM and patients prescribed TTFT treatment will have to continue that treatment for the rest of their hopefully extended lives.

**B. The Medicare Appeals Process**

16. Claims submitted by beneficiaries enrolled in Original Medicare are subject to a five (5) level appeal process, that can (and typically does) take more than a year. At the first stage, a beneficiary submits a claim. If the claim is denied, the beneficiary can request “redetermination.” If the claim is still denied, the beneficiary can request “reconsideration.” If the claim is still denied, the beneficiary can appeal to an ALJ. If the ALJ denies the claim, the beneficiary can appeal to the Medicare Appeals Council. Finally, if the claim is still denied, the beneficiary can file suit in district court.

17. While the statutes and regulations require both ALJs and the MAC to issue decisions within 90 days, those deadlines are routinely missed. Thus, beneficiaries seeking coverage are often thrown into a multi-year effort to obtain final decisions in their cases before they can seek relief in a federal court.

**C. Mrs. Piekanski**

18. Mrs. Piekanski is a 65-year-old retired grocery store worker, mother/step-mother of four (4), and grandmother to ten (10). Along with her husband of more than 20 years (Theodore), Mrs. Piekanski currently lives in Throop,

Pennsylvania – just outside of Scranton. In her free time, Mrs. Piekanski enjoys music and spending time with her family.

19. Mrs. Piekanski was diagnosed with GBM in 2011 and, after surgery and chemo-radiation, Mrs. Piekanski began using the Optune device in August 2011.

***(i) Prior TTFT Coverage Decisions Favorable to Mrs. Piekanski That Have Become Final***

**Appeal No. 1-7835229465**

20. On November 7, 2018, ALJ Jeffrey Gulin issued a Decision on Medicare claims related to TTFT to treat Mrs. Piekanski's GBM during the months of September, October, and November 2018, finding that coverage was appropriate. Among other findings, Judge Gulin found that TTFT treatment was safe and effective and medically reasonable and necessary for Mrs. Piekanski. Thus, Judge Gulin ordered coverage of Mrs. Piekanski's claims. Of note, the Secretary chose not to participate in the hearing conducted by Judge Gulin or to submit briefs.

21. The Secretary did not appeal Judge Gulin's decision and the decision became final on January 7, 2019.

**Appeal No. 1-8637781229**

22. On September 13, 2019, ALJ Ryan Glaze issued a Decision on Medicare claims related to TTFT to treat Mrs. Piekanski's GBM during the months of June, July, and August 2018 finding that coverage was appropriate. Among other



findings, Judge Glaze found: 1) that Mrs. Piekanski's GBM was "newly diagnosed" (as opposed to "recurrent"); and 2) that TTFT treatment was safe and effective and medically reasonable and necessary for Mrs. Piekanski. Thus, Judge Glaze ordered coverage of Mrs. Piekanski's claims. Of note, the Secretary chose not to participate in the hearing conducted by Judge Glaze or to submit briefs.

23. The Secretary did not appeal Judge Glaze's decision and the decision became final on November 13, 2019.

**Appeal No. 1-8415573880**

24. On June 4, 2019, ALJ Jenifer Soulikias issued a Decision on Medicare claims related to TTFT to treat Mrs. Piekanski's GBM during the months of September, October, and November 2018 finding that coverage was appropriate. Among other findings, Judge Soulikias found that TTFT treatment was safe and effective and medically reasonable and necessary for Mrs. Piekanski. Thus, Judge Soulikias ordered coverage of Mrs. Piekanski's claims. Of note, the Secretary chose not to participate in the hearing conducted by Judge Soulikias or to submit briefs.

25. The Secretary did not appeal Judge Soulikias' decision and the decision became final on August 4, 2019.

**Appeal No. 3-8925380171**

26. More recently, on January 29, 2020, ALJ James Myles issued a Decision on Medicare claims related to TTFT to treat Mrs. Piekanski's GBM during

the months of March, April, and May 2019, finding that coverage was appropriate. Among other findings, Judge Myles concluded that TTFT was medically reasonable and necessary for Mrs. Piekanski. Therefore, Judge Myles ordered coverage of her claims. Notably, the Secretary chose not to participate in the hearing or submit briefs.

27. The Secretary did not appeal Judge Myles' decision and the decision became final on March 29, 2020.

***(ii) The Decision Denying Coverage Being Appealed In This Case.***

**Appeal No. 1-8071086400R1**  
**Docket No. M-19-2250**

28. On January 18, 2019, ALJ Glaze issued a Decision in Appeal No. 1-8071086400 (subsequently No. 1-8071086400R1), Medicare Appeals Council Docket No. M-19-2250, as to Medicare claims related to TTFT to treat Mrs. Piekanski's GBM during the months of December 2017 through February 2018. There, contrary to the decisions issued above, Judge Glaze held that Mrs. Piekanski was not entitled to coverage. For example, contrary to the decision issued in September 2019, *e.g.*, Judge Glaze held that Mrs. Piekanski's GBM was considered "recurrent" rather than "newly diagnosed." Again, contrary to the decisions listed above, Judge Glaze held that TTFT was not medically reasonable and necessary for Mrs. Piekanski.

29. Mrs. Piekanski timely appealed. In particular, Mrs. Piekanski noted the prior decisions from ALJs Gulin, Glaze, and Soulikias finding coverage appropriate. As a result, Mrs. Piekanski argued that the Secretary was collaterally estopped from re-litigating that issue.

30. When the Secretary did not issue a decision with the 90-day time frame provided by 42 U.S.C. § 1395ff(d)(2)(A), pursuant to 42 C.F.R. § 405.1132, Mrs. Piekanski filed a notice of escalation on November 15, 2019 again arguing that the Secretary was collaterally estopped from denying coverage. When no response was received within the 5-day time limit of 42 C.F.R. § 405.1132(a)(1), ALJ Glaze's decision became the final decision of the Secretary ("Secretary's Final Decision") and Mrs. Piekanski timely filed this suit.

## **CAUSES OF ACTION**

### **COUNT I**

#### **Violation of 42 U.S.C. § 405(g) (contrary to law)**

31. Plaintiff hereby incorporates paragraphs 1-30 as if fully set forth herein.

32. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Final Decision as contrary to law, as arbitrary and capricious, an abuse of discretion, and unsupported by the evidence; and issue an order finding that Plaintiff's claims are covered and directing the Secretary to make appropriate payment for the claims that are the subject of this case.

**COUNT II**

**Violation of 5 U.S.C. § 706(1)**

(unlawfully withheld or unreasonably delayed)

33. Plaintiff hereby incorporates paragraphs 1-32 as if fully set forth herein.

34. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Final Decision as unlawfully withheld or unreasonably delayed and unsupported by the evidence; and issue an order finding that Plaintiff's claims are covered and directing the Secretary to make appropriate payment for the claims that are the subject of this case.

**COUNT III**

**Violation of 5 U.S.C § 706(2)(A)**

(arbitrary and capricious, abuse of discretion, not in accordance with law)

35. Plaintiff hereby incorporates paragraphs 1-34 as if fully set forth herein.

36. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Final Decision as arbitrary and capricious, an abuse of discretion, and otherwise not in accordance with the law; and issue an order finding that Plaintiff's claims are covered and directing the Secretary to make appropriate payment for the claims that are the subject of this case.

**COUNT IV**

**Violation of 5 U.S.C § 706(2)(C)**

(in excess of statutory jurisdiction, authority, or  
limitations or short of statutory right)

37. Plaintiff hereby incorporates paragraphs 1-36 as if fully set forth herein.

38. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Final Decision as in excess of the Secretary's authority and limitations and short of Plaintiff's statutory rights; and issue an order finding that Plaintiff's claims are covered and directing the Secretary to make appropriate payment for the claims that are the subject of this case.

**COUNT V**  
**Violation of 5 U.S.C § 706(2)(D)**  
(without observance of procedure required by law)

39. Plaintiff hereby incorporates paragraphs 1-38 as if fully set forth herein.

40. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Final Decision as done without observance of the procedure required by law; and issue an order finding that Plaintiff's claims are covered and directing the Secretary to make appropriate payment for the claims that are the subject of this case.

**COUNT VI**  
**Violation of 5 U.S.C § 706(2)(E)**  
(not supported by substantial evidence)

41. Plaintiff hereby incorporates paragraphs 1-40 as if fully set forth herein.

42. Based on the foregoing, Plaintiff asks the Court to reverse the Secretary's Final Decision as not supported by substantial evidence; and issue an order finding that Plaintiff's claims are covered and directing the Secretary to make appropriate payment for the claims that are the subject of this case.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiff asks that this Court:

A. Enter an order:

(1) finding that the Secretary is collaterally estopped from relitigating whether TTFT treatment for Plaintiff is a covered benefit;

(2) finding that, in light of the prior decisions granting coverage, the denial at issue in this case are arbitrary and capricious;

(3) directing the Secretary to cover the claims at issue in this case;

B. Award attorney's fees and costs to Plaintiff as permitted by law; and

C. Provide such further and other relief this Court deems appropriate.

Respectfully submitted,

/s/ Mark W. Fidanza

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*Attorney for Plaintiff*

*Maureen Piekanski*

Dated: June 12, 2020

**CERTIFICATE OF SERVICE**

I, Mark W. Fidanza, certify that a true and correct copy of the foregoing First Amended Complaint was filed electronically on June 12, 2020, is available for viewing and downloading from the federal court's ECF/CM system, and will be automatically served upon registered counsel of record by ECF/CM.

/s/ Mark W. Fidanza

Mark W. Fidanza